MAR 1 2 2014

510(k) Notification K132080

GENERAL INFORMATION

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Date Prepared: March 10, 2014

DEVICE INFORMATION

Classification:
21CFR§878.4683, Class II

Product Code:
OKO, Negative Pressure Wound Therapy Non-Powered Suction Apparatus

Trade Name:
SNaP® Wound Care System

Generic/Common Name:
Non-powered suction apparatus device intended for negative pressure wound therapy

Predicate Device
SNaP® Wound Care System (K081406, K111393, K112341, K113032)

Intended Use

The SNaP Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

PRODUCT DESCRIPTION

The SNaP® Wound Care System ("SNaP System") is an existing (K081406, K111393, K112341, K113032) non-powered, portable, single-use suction device intended for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The SNaP System utilizes dedicated constant-force springs to mechanically generate the negative pressure gradient. The proposed SNaP Wound Care System will have the same indication for use as the predicate device, the SNaP Wound Care System (K113032). In addition, Spiracur has added the SNaP® Bridge Dressing Kit ("SNaP Bridge Dressing") and SNaP® SecurRing™ Hydrocolloid ("SNaP SecurRing") to the SNaP Dressing Kit product family.

SUBSTANTIAL EQUIVALENCE

The proposed labeling changes did not result in any design modifications to the cleared SNaP Wound Care System (K081406, K111393, K112341, K113032). The only modifications resulting from the labeling changes are to the SNaP System Instructions for Use provided to the physician, that now describes conditions for use of the SNaP System dressing components within enriched oxygen environments, such as hyperbaric oxygen (HBO) chambers, and also now includes instructions for resetting the SNaP Wound Care Cartridge. In addition, Spiracur has added the SNaP Bridge Dressing and SNaP SecurRing to the SNaP Dressing Kit product family. The SNaP Bridge Dressing is a design modification introduced to the SNaP Foam Dressing Kit (K112341) to facilitate dressing use on a variety of anatomical contours. The sterile, moldable hydrocolloid SNaP SecurRing serves the same function as the hydrocolloid layer of standard SNaP Dressing, to improve the seal of the dressing around the wound.

The additions of the SNaP Bridge Dressing Kit and the SNaP SecurRing to the SNaP Dressing Kit product family are to provide clinicians additional dressing options for use with the SNaP System, designed to help achieve a seal during the SNaP Dressing application. The additions to the SNaP Dressing Kit product family are substantially equivalent to existing items of the product family as they have the same intended use in the same wound types, and utilize similar performance specifications and comparable technological features to achieve the same mechanism of action: therefore, the additions do not raise any new issues of safety or effectiveness.

The SNaP System is substantially equivalent to the predicate device as both devices have the same intended use, have been historically cleared for use in the same wound types, and utilize similar performance specifications and comparable technological features to achieve the same

mechanism of action: therefore, the modified labeling does not raise any new issues of safety or effectiveness.

Testing in Support of Substantial Equivalence Determination

To support the additions of the SNaP Bridge Dressing Kit and the SNaP SecurRing to the SNaP Dressing Kit product family, Spiracur conducted necessary bench testing to ensure conformance to design specifications and to support a determination of substantial equivalence to existing items of the SNaP Dressing Kit product family. The testing performed includes:

- Verification testing
- Simulated wound performance testing
- Biocompatibility testing
- Packaging and shelf life testing

The proposed labeling changes to the cleared SNaP Wound Care System did not result in any design modifications. All necessary bench testing was conducted on the SNaP Wound Care System and its components to ensure conformance to design specifications and to support a determination of substantial equivalence to the predicate device. The testing performed includes:

- Bench testing within a simulated hyperbaric oxygen environment to characterize the probability of self-ignition and to characterize the potential severity of ignition of the SNaP Wound Care dressing materials, in order to evaluate the oxygen compatibility of the dressing materials.
- Bench testing conducted in conjunction with the modified device Instructions for Use to evaluate the functionality of a latent design feature allowing for the resetting of the SNaP Wound Care System to assess the ability of the SNaP Wound Care System to deliver negative pressure wound therapy comparable to the predicate device (K081406, K111393, K112341, K113032).
- Simulated wound performance testing conducted in conjunction with the modified device Instructions for Use to evaluate the functionality of a latent design feature allowing for the resetting of the SNaP Wound Care System to assess the ability of the SNaP Wound Care System to deliver negative pressure wound therapy comparable to the predicate device (K081406, K111393, K112341, K113032) when used in conjunction with the SNaP Bridge Dressing Kit and the SNaP SecurRing and all other dressing configurations after resetting.

SUMMARY

The SNaP® Wound Care System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2014

Spiracur Incorporated
% Ms. Sarah L. Canio
Experien Group, LLC
755 North Mathilda Avenue
Sunnyvale, California 94085

Re: K132080
Trade/Device Name: SNaP® Wound Care System
Regulation Number: 21 CFR 878.4683
Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy
Regulatory Class: Class II
Product Code: OKO
Dated: February 7, 2014
Received: February 10, 2014

Dear Ms. Canio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132080

Device Name
SNaP® Wound Care System

Indications for Use *(Describe)*
The SNaP® Wound Care System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of excess exudate, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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